

AMENDED IN SENATE AUGUST 22, 2012  
AMENDED IN SENATE AUGUST 7, 2012  
AMENDED IN ASSEMBLY MAY 30, 2012  
AMENDED IN ASSEMBLY MAY 8, 2012  
AMENDED IN ASSEMBLY APRIL 25, 2012  
AMENDED IN ASSEMBLY MARCH 29, 2012

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

## **ASSEMBLY BILL**

**No. 2356**

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**Introduced by Assembly Member Skinner**

February 24, 2012

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An act to amend Section 1644.5 of, and to add Section 1644.6 to, the Health and Safety Code, relating to human tissue.

### LEGISLATIVE COUNSEL'S DIGEST

AB 2356, as amended, Skinner. Tissue donation.

Existing law prohibits the transfer of any tissues, as defined, into the body of another person by means of transplantation, unless the donor of the tissues has been screened and found nonreactive for evidence of infection with human immunodeficiency virus (HIV), agents of viral hepatitis (HBV and HCV), syphilis, and human T lymphotropic virus (HTLV), except as provided. Existing law requires that all donors of sperm be screened and found nonreactive under the above provisions, except as provided.

This bill would except sperm donated by a sexually intimate partner of the recipient, as defined, from second or repeat testing under these requirements if the recipient is informed of the testing requirements

and signs a written waiver, as specified. This bill would exclude a physician and surgeon from liability for any cause of action based solely upon the use of sperm from a sexually intimate partner of the recipient when the physician and surgeon provides insemination or assisted reproductive technology services and has obtained the informed consent of the recipient, who *waives 2nd or other repeat testing of the sexually intimate partner and* acknowledges and accepts the risks of using sperm ~~that from a sexually intimate partner who has not undergone quarantine~~ and repeat testing, as described. The bill would exclude a physician and surgeon from disciplinary action because the physician and surgeon used sperm in these conditions in providing insemination or assisted reproductive technology services.

The bill would exclude a physician and surgeon owned and operated clinical laboratory or tissue bank from disciplinary action for providing these insemination or assisted reproductive technology services.

The bill would also provide that some of its provisions do not create a duty for a physician and surgeon to use sperm from a sexually intimate partner of the recipient in providing insemination or assisted reproductive technology services if the physician and surgeon determines that the insemination or services do not meet specified guidelines for providing insemination or assisted reproductive technology services.

This bill would replace references to advanced reproductive technologies and advanced reproductive technology services with assisted reproductive technologies and assisted reproductive technology services.

Vote: majority. Appropriation: no. Fiscal committee: no.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

- 1 SECTION 1. The Legislature finds and declares all of the
- 2 following:
- 3 (a) Single women and same-sex female couples using a known
- 4 donor are unable to access the same fertility services as women
- 5 seeking to conceive using a male partner.
- 6 (b) Women seeking fertility services to help them conceive with
- 7 a male partner are able to be inseminated using fresh sperm.
- 8 Because of the practical difficulty of performing the required
- 9 testing and fears of liability, most fertility services will not provide

1 fresh insemination services to a woman using a donor who is not  
2 her partner.

3 (c) All other women are required to have their donors' sperm  
4 frozen, which significantly reduces the chance of conceiving and,  
5 for many donors, means that conception is not possible without  
6 much more expensive procedures.

7 (d) Federal Food and Drug Administration (FDA) regulations  
8 require extensive testing, except when the donor is a "sexually  
9 intimate partner" (21 C.F.R. 1271.90). This term is not defined in  
10 regulations. Based upon the term's ordinary meaning, the term has  
11 been construed to apply to heterosexual couples with an ongoing  
12 relationship. Because the explicit purpose of the term is to allow  
13 donation without testing when the recipient has already been  
14 exposed, this term can be interpreted to include women who have  
15 already attempted at-home inseminations with their donors' sperm  
16 because they have already been exposed through these attempts.

17 (e) Although California requires testing in all circumstances,  
18 the state authorizes waivers of repeat testing for sperm donors  
19 known to the recipient.

20 (f) Until the term "sexually intimate partner" is explicitly defined  
21 by the FDA, it is the intent of the Legislature to provide a  
22 clarification that, for the purposes of tissues donated for  
23 reproductive use, a "sexually intimate partner" includes a known  
24 or designated donor to whose sperm the recipient has previously  
25 been exposed in a nonmedical setting in an attempt to conceive.

26 (g) It is also the intent of the Legislature to address the potential  
27 for confusion amongst treating professionals regarding prevailing  
28 regulations and professional guidelines that reference both the  
29 term "sexually intimate partner" and the term "known donor." Due  
30 to this potential, and in recognition that there are multiple entities  
31 that regulate physicians and surgeons and the area of assisted  
32 reproductive technologies for which the physician or surgeon is  
33 accountable, it is the intent of the Legislature to provide physicians  
34 and surgeons with immunity when acting in a manner consistent  
35 with this law. Both the physician and surgeon who believes this  
36 act and the standard of care allows the use of fresh sperm from a  
37 known donor to which the woman has already been exposed  
38 constitutes a "sexually intimate partner" and the physician and  
39 surgeon who believes that the use of fresh sperm in this situation  
40 is a violation of professional guidelines and declines to use fresh

1 sperm need assurances that their actions under this new law would  
2 not be subjecting themselves to additional professional risk.

3 (h) The definition of “sexually intimate partner” is limited to  
4 this act and is not intended to have any effect on any provision of  
5 the Family Code, including the definition of a “donor” for purposes  
6 of determining legal parentage of a child.

7 (i) It is not the intent of the Legislature to prevent federal  
8 regulators from exercising federal authority over facilities that  
9 provide insemination or assisted reproductive technology services.

10 SEC. 2. Section 1644.5 of the Health and Safety Code is  
11 amended to read:

12 1644.5. (a) Except as provided in subdivision (c) or (d), no  
13 tissues shall be transferred into the body of another person by  
14 means of transplantation, unless the donor of the tissues has been  
15 screened and found nonreactive by laboratory tests for evidence  
16 of infection with human immunodeficiency virus (HIV), agents  
17 of viral hepatitis (HBV and HCV), and syphilis. For tissues that  
18 are rich in viable leukocytes, the tissue shall be tested for evidence  
19 of infection with human T lymphotropic virus (HTLV) and found  
20 nonreactive. The department may adopt regulations requiring  
21 additional screening tests of donors of tissues when, in the opinion  
22 of the department, the action is necessary for the protection of the  
23 public, donors, or recipients.

24 (b) Notwithstanding subdivision (a), infectious disease screening  
25 of blood and blood products shall be carried out solely in  
26 accordance with Article 2 (commencing with Section 1602.5) of  
27 Chapter 4.

28 (c) All donors of sperm shall be screened and found nonreactive  
29 as required under subdivision (a), except in the following instances:

30 (1) A recipient of sperm, from a sperm donor known to the  
31 recipient, may waive a second or other repeat testing of that donor  
32 if the recipient is informed of the requirements for testing donors  
33 under this section and signs a written waiver.

34 (2) A recipient of sperm may consent to therapeutic insemination  
35 of sperm or use of sperm in other assisted reproductive technologies  
36 even if the sperm donor is found reactive for hepatitis B, hepatitis  
37 C, syphilis, HIV, or HTLV if the sperm donor is the spouse of,  
38 partner of, or designated donor for that recipient. The physician  
39 providing insemination or assisted reproductive technology services  
40 shall advise the donor and recipient of the potential medical risks

1 associated with receiving sperm from a reactive donor. The donor  
2 and the recipient shall sign a document affirming that each  
3 comprehends the potential medical risks of using sperm from a  
4 reactive donor for the proposed procedure and that each consents  
5 to it. Copies of the document shall be placed in the medical records  
6 of the donor and the recipient.

7 (3) (A) Sperm whose donor has tested reactive for syphilis may  
8 be used for the purposes of insemination or assisted reproductive  
9 technology only after the donor has been treated for syphilis. Sperm  
10 whose donor has tested reactive for hepatitis B may be used for  
11 the purposes of insemination or assisted reproductive technology  
12 only after the recipient has been vaccinated against hepatitis B.

13 (B) (i) Sperm whose donor has tested reactive for HIV or HTLV  
14 may be used for the purposes of insemination or assisted  
15 reproductive technology for a recipient testing negative for HIV  
16 or HTLV only after the donor's sperm has been effectively  
17 processed to minimize the infectiousness of the sperm for that  
18 specific donation and where informed and mutual consent has  
19 occurred.

20 (ii) Not later than January 1, 2014, the department shall adopt  
21 regulations regulating facilities that perform sperm processing,  
22 pursuant to this subparagraph, that prescribe standards for the  
23 handling and storage of sperm samples of carriers of HIV, HTLV,  
24 or any other virus as deemed appropriate by the department. The  
25 department may propose to adopt, as initial regulations, the  
26 recommendations made within the "Guidelines for Reducing Risk  
27 of Viral Transmission During Fertility Treatment" as published  
28 by the American Society for Reproductive Medicine. Notice of  
29 the department's proposed adoption of the regulations shall be  
30 posted on the department's Internet Web site for at least 45 days.  
31 Public comment shall be accepted by the department for at least  
32 30 days after the conclusion of the 45-day posting period. If a  
33 member of the public requests a public hearing during the 30-day  
34 comment period, the hearing shall be held prior to the adoption of  
35 the regulations. If no member of the public requests a public  
36 hearing, the regulations shall be deemed adopted at the conclusion  
37 of the 30-day comment period. Comments received shall be  
38 considered prior to the adoption of the final initial regulations. The  
39 department may modify any guidance published by the American  
40 Society for Reproductive Medicine. Adoption of initial regulations

1 by the department pursuant to this subdivision shall not be subject  
2 to the rulemaking requirements of Chapter 3.5 (commencing with  
3 Section 11340) of Part 1 of Division 3 of Title 2 of the Government  
4 Code and written responses to public comments shall not be  
5 required. Updates to the regulations shall be adopted pursuant to  
6 the same process. Until the department adopts these regulations,  
7 facilities that perform sperm processing pursuant to this section  
8 shall follow facility and sperm processing guidelines for the  
9 reduction of viral transmission developed by the American Society  
10 for Reproductive Medicine. Nothing in this section shall prevent  
11 the department from monitoring and inspecting facilities that  
12 process sperm to ensure adherence to the regulations, or, until  
13 regulations are adopted, to the guidelines set forth by the American  
14 Society for Reproductive Medicine.

15 (iii) Prior to insemination or other assisted reproductive  
16 technology services, the physician providing the services shall  
17 inform the recipient of sperm from a spouse, partner, or designated  
18 donor who has tested reactive for HIV or HTLV of all of the  
19 following:

20 (I) That sperm processing may not eliminate all of the risks of  
21 HIV or HTLV transmission.

22 (II) That the sperm may be tested to determine whether or not  
23 it is reactive for HIV or HTLV.

24 (III) That the recipient must provide documentation to the  
25 physician providing insemination or assisted reproductive  
26 technology services prior to treatment that she has established an  
27 ongoing relationship with another physician to provide for her  
28 medical care during and after completion of fertility services.

29 (IV) The recommendations made within the “Guidelines for  
30 Reducing the Risk of Viral Transmission During Fertility  
31 Treatment” published by the American Society for Reproductive  
32 Medicine regarding followup testing for HIV and HTLV after use  
33 of sperm from an HIV or HTLV reactive donor and have the  
34 recommendations regarding followup testing be documented in  
35 the recipient’s medical record.

36 (iv) The physician providing insemination or assisted  
37 reproductive technology services shall also verify, and document  
38 in the recipient’s medical record, that the donor of sperm who tests  
39 reactive for HIV or HTLV is under the care of a physician  
40 managing the HIV or HTLV.

(v) The physician providing insemination or assisted reproductive technology services shall recommend to the physician who will be providing ongoing care to the recipient recommended followup testing for HIV and HTLV according to the “Guidelines for Reducing the Risk of Viral Transmission During Fertility Treatment” published by the American Society for Reproductive Medicine, which shall be documented in the recipient’s medical record.

(vi) In the event that the recipient becomes HIV or HTLV positive, the physician assuming ongoing care of the recipient shall treat or provide information regarding referral to a physician who can provide ongoing treatment of the HIV or HTLV.

(4) A recipient of sperm donated by a sexually intimate partner of the recipient for reproductive use may waive a second or repeat testing of that donor if the recipient is informed of the donor testing requirements of this section and signs a written waiver. For purposes of this paragraph, “sexually intimate partner of the recipient” includes a known or designated donor to whose sperm the recipient has previously been exposed in a nonmedical setting in an attempt to conceive.

(d) Subdivision (a) shall not apply to the transplantation of tissue from a donor who has not been tested or, with the exception of HIV and HTLV, has been found reactive for the infectious diseases listed in subdivision (a) or for which the department has, by regulation, required additional screening tests, if both of the following conditions are satisfied:

(1) The physician and surgeon performing the transplantation has determined any one or more of the following:

(A) Without the transplantation the intended recipient will most likely die during the period of time necessary to obtain other tissue or to conduct the required tests.

(B) The intended recipient already is diagnosed with the infectious disease for which the donor has tested positive.

(C) The symptoms from the infectious disease for which the donor has tested positive will most likely not appear during the intended recipient’s likely lifespan after transplantation with the tissue or may be treated prophylactically if they do appear.

(2) Consent for the use of the tissue has been obtained from the recipient, if possible, or if not possible, from a member of the recipient’s family, or the recipient’s legal guardian. For purposes

1 of this section, “family” shall mean spouse, adult son or daughter,  
2 either parent, adult brother or sister, or grandparent.

3 (e) The penalties of Section 1621.5 shall not apply to a sperm  
4 donor covered under subdivision (c).

5 (f) Human breast milk from donors who test reactive for agents  
6 of viral hepatitis (HBV and HCV), HTLV, HIV, or syphilis shall  
7 not be used for deposit into a milk bank for human ingestion in  
8 California.

9 SEC. 3. Section 1644.6 is added to the Health and Safety Code,  
10 to read:

11 1644.6. (a) No physician and surgeon shall be subject to  
12 liability for damages for any cause of action based solely on the  
13 use of sperm donated by a sexually intimate partner of the recipient  
14 ~~when the physician~~ *if both of the following conditions are met:*

15 (1) *The physician and surgeon provides insemination or assisted*  
16 *reproductive technology services and has obtained the informed*  
17 *consent of the recipient, who waives second or other repeat testing*  
18 *of the sexually intimate partner and acknowledges and accepts the*  
19 *risks of using sperm that from a sexually intimate partner who has*  
20 *not undergone quarantine and repeat testing, as described in in*  
21 *accordance with paragraph (1) of subdivision (c) of Section*  
22 *1644.5.*

23 (2) *The physician and surgeon complies with the applicable*  
24 *requirements specified in Section 1644.5.*

25 (b) No physician and surgeon shall be subject to disciplinary  
26 action against his or her professional license, or subject to peer  
27 review by a professional association peer review body, as defined  
28 in clause (iii) of subparagraph (B) of paragraph (1) of subdivision  
29 (a) of Section 805 of the Business and Professions Code, because  
30 the physician and surgeon used sperm donated by a sexually  
31 intimate partner of the recipient in providing insemination or  
32 assisted reproductive technology services ~~when the~~ *if both of the*  
33 *following conditions are met:*

34 (1) *The physician and surgeon has obtained the informed consent*  
35 *of the recipient who waives second or other repeat testing of the*  
36 *sexually intimate partner and acknowledges and accepts the risks*  
37 *of using sperm that from a sexually intimate partner who has not*  
38 *undergone quarantine and repeat testing, as described in in*  
39 *accordance with paragraph (1) of subdivision (c) of Section*  
40 *1644.5.*

1     (2) *The physician and surgeon complies with the applicable*  
2 *requirements specified in Section 1644.5.*

3     (c) A clinical laboratory that is owned and operated by a  
4 physician and surgeon or a tissue bank that is owned and operated  
5 by a physician and surgeon shall not be subject to disciplinary  
6 action against its license because of the use of sperm donated by  
7 a sexually intimate partner of the recipient in providing  
8 insemination or assisted reproductive technology services ~~when~~  
9 ~~any~~ *if both of the following conditions are met:*

10     (1) A physician and surgeon affiliated with the clinical laboratory  
11 or tissue bank has obtained the informed consent of the recipient,  
12 who *waives second or other repeat testing of the sexually intimate*  
13 *partner and* acknowledges and accepts the risks of using sperm  
14 ~~that from a sexually intimate partner who~~ has not undergone  
15 ~~quarantine and repeat testing, as described in accordance with~~  
16 *paragraph (1) of subdivision (c) of Section 1644.5.*

17     (2) *The physician and surgeon complies with the applicable*  
18 *requirements specified in Section 1644.5.*

19     (d) Nothing in this section shall create a duty for a physician  
20 and surgeon to use sperm donated by a sexually intimate partner  
21 of the recipient in providing insemination or assisted reproductive  
22 technology services if the physician and surgeon reasonably  
23 concludes that the insemination or services do not meet the 2008  
24 American Society for Reproductive Medicine guidelines for gamete  
25 and embryo donation.

26     (e) Nothing in this section shall be construed to affect any  
27 liability that may be imposed pursuant to a federal rule or  
28 regulation when a physician and surgeon, clinical laboratory, or  
29 tissue bank provides insemination or assisted reproductive  
30 technology services.

31     (f) For purposes of this section, “sexually intimate partner”  
32 includes a known or designated donor to whose sperm the recipient  
33 has previously been exposed in a nonmedical setting in an attempt  
34 to conceive.